REMARKS

Upon entry of this amendment, claims 1, 2, 4, 6-10, 17-18 and 60-69 are pending in the application. Claims 3, 5, 16, and 19-59 are canceled. Claims 1, 2, 8, 17, and 18 have been amended. Claim 8 has been amended to correct a typographical error. Claims 17 and 18 have been amended for proper antecedent basis. Support for the amendments to claims 1 and 2 can be found throughout the specification and in the originally filed claims, *e.g.*, at least in original claim 16; at Figure 1; and at page 12, lines 5-8 and 18-22; and Example 1 of the specification as-filed. New claims 60-69 have been added. Support for new claims 60-69 can be found throughout the specification and in the originally filed claims, *e.g.*, at least at page 1, lines 17-25; and at page 12, lines 1-22 of the specification as-filed. The specification has been amended to consecutively number Examples 3, 4, 5, and 6 in the specification. No new matter has been added.

Claim 1 has been amended to require that the diagnosis of multiple sclerosis (MS) is after the first neurological attack and prior to a second neurological attack. Multiple Sclerosis (MS) is a neurological disease characterized by deterioration of the myelin sheath of axons. Prior to the invention, MS could be diagnosed and treated only after a second neurological attack, at which point significant damage to the myelin sheath has already occurred. The physician has to determine if the patient has MS-like symptoms (such as Younger stroke, Lupus, Vitamin B-12 deficiency, Anti phospholipid syndrome, Severe Migraine) or if they actually have MS. (*See* Specification at page 12, lines 3-5.) Utilizing the claimed methods, a patient is diagnosed as an MS patient without the need to wait for a second attack. Applicants' invention represents a significant development in the diagnosis and treatment of the disease so that treatment can be implemented prior to the development of significant nerve damage. Anti-Glc (α 1-4) Glc

(α) IgM type antibodies are detected in a test sample, *e.g.*, a blood sample, taken from an individual after a first attack, but before a second neurological attack. Thus, the method provides the ability to diagnose MS early in the disease course, *i.e.*, before significant myelin damage has occurred, to permit implementation of treatment to prevent development of significant nerve damage and concomitant debilitating symptoms.

Rejections under 35 USC § 112, Second Paragraph

Claim 16 is rejected as being indefinite. (*See* Office Action at page 3.) Claim 16 has been canceled. This rejection should be withdrawn.

Rejections under 35 USC § 112, First Paragraph

Claims 1-20 and 22-45 are rejected for lack of enablement. Claims 3, 5, 16, and 19-45 have been canceled. The rejection is traversed to the extent it is applied to the remaining claims as amended.

The claims have been amended to specify isotypes of the recited antibodies that are shown in the specification to correlate with disease status as disclosed in the specification. Specifically, claim 1, from which the remaining claims subject to the rejection depend, directly or indirectly, recites, in relevant part, a method of diagnosing MS in a subject by detecting in a test sample from a subject an anti-Glc (α 1-4) Glc (α) IgM type antibody and comparing the levels of the antibody in the test sample to the levels of the antibody in a normal control sample. Similarly, claim 2, which depends from claim 1, further comprises detection of an anti-Glc(α) IgM type antibody, which correlates with disease status. (*See* Specification at Example 2.)

Applicants submit that the specification fully enables the claimed invention and provides examples illustrating the methods the claims. For example, in summarizing the data in Fig. 5, Example 1 recites that the median signal to anti-Glc (α1-4) Glc (α) in the MS group was higher than the signal in the normal control group. (*See* Specification at Example 1.) Moreover, Example 2 of the specification recites that the levels of IgM anti-Glc(α) and anti-Glc(α1-4) Glc(α) antibodies were higher in the MS group as compared to the healthy group. (*See* Specification at page 18, lines 4-8; and at Figure 7.)

The Examiner also contends that the claims require undue experimentation in light of Schwartz *et al.*, J. Neuro. Sci. 244:59-68, 2006 ("Schwarz"). Applicants traverse.

As stated above, claim 1, from which the remaining claims subject to the rejection depend, directly or indirectly, now requires the identification of anti-Glc (α1-4) Glc (α) IgM type antibody, after the first neurological attack and prior to a second neurological attack. Schwartz does not describe the identification of anti-Glc (α1-4) Glc (α) IgM type antibody during this time frame, *i.e.*, after the first neurological attack and prior to a second neurological attack. The Schwartz reference describes patients with fully-developed classic MS and reports that there were significantly higher levels of anti-Glc (α1-4) Glc (α) IgM type antibodies in patients with relapsing-remitting MS (RRMS) than in patients suffering from other neurological diseases (OND) and other autoimmune diseases (OAD).

In view of the foregoing comments, Applicants request withdrawal of the rejection for lack of enablement.

Double patenting rejections

Claims 1-20 and 22-45 are provisionally rejected for obviousness-type double patenting over claims 1-20 and 22-45 of U.S. Application No. 10/835,607. Applicants will address this rejection upon the indication of allowable subject matter in either application.

Claims 1-20 and 22-45 are provisionally rejected for obviousness-type double patenting over claims 1-20 and 22-45 of U.S. Application No. 11/047,124. Applicants will address this rejection upon the indication of allowable subject matter in either application.

Applicants submit that the application is in condition for allowance, and request a Notice for same. Please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Ref. No. 25681-501 UTIL.

Respectfully submitted,

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